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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,367	01/23/2002	Michael Affolter	112843-029	4325

29174 7590 11/07/2006

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,367	AFFOLTER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Raw sequence listing error report .

DETAILED ACTION

Status of the Claims

1. Claims 1-18 are pending.

Applicants' amendment filed August 28, 2006 is acknowledged. Applicants' response has been fully considered. Claims 7 and 16-18 have been amended. Claims 1-6 and 9-13 are non-elected inventions and withdrawn from consideration. Therefore, claims 7, 8 and 14-18 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claim 16 under 35 U.S.C. 112, first paragraph, regarding the deposited material, is withdrawn in view of applicants' amendment to the specification, applicants' submission of CNCM notification of receipt, and applicants' response at page 8 in the amendment filed August 28, 2006.

3. The previous rejection of claims 7, 17 and 18 under 35 U.S.C. 112, second paragraph, regarding the term "the creA gene" or "the areA gene", is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 9 in the amendment filed August 28, 2006.

Maintained Informalities

The disclosure is objected to because of the following informalities:

4. A paper copy and computer readable form of Sequence Listing have been filed on August 28, 2006, however, some errors were found in the Raw Sequence Error Report (see attached). Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a paper copy and computer readable form of Sequence Listing.

The amendment to the specification regarding the "SEQ ID NO:" is acknowledged.

Claim Objections

5. Claim 16 is objected to because of the use of the term "wherein the koji mold is Aspergillus oryzae I-2145 (NF14)". Since the recited term refers to a deposited material of CNCM, thus it is suggested to use "CNCM I-2145" instead of "I-2145" . Appropriate correction is required.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7, 8 and 14-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 8 and 14-18 are directed to a method for hydrolyzing protein-containing materials or a method of preparing a protein hydrolysate comprising hydrolyzing a proteinaceous material with a Koji mold belonging to the genus Aspergillus, Rhizopus, Mucor, or Penicillium, the proteolytic activity of which is not carbon repressed and wherein a creA gene has been mutated such that the gene product thereof is essentially nonfunctional. While the specification describes the creA gene can be specifically modified such that a non-functional gene product can be obtained and would not block the transcription of protease, and a creA mutation may be

combined with an increased production of the areA gene, a positive stimulator for the production of protease (pages 4-5), the specification does not disclose a method for hydrolyzing protein-containing materials by contacting a proteinaceous material with a Koji mold having a modified creA gene, nor indicates a protein hydrolysate produced by the method. Furthermore, the specification does not disclose the use of creA mutant in combination with an enzyme or microorganism having a prolidase activity, or the use of a functional derivative of areA gene in the claimed method. The specification merely shows the isolation of creA mutant, isolation of the creA gene, modification of the creA gene, and test for mutation of creA gene (Examples 1-5), there is no example indicating the claimed methods using the mutated creA gene. The lack of description of the method steps for the claimed methods and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate methods for hydrolyzing protein-containing materials by contacting a proteinaceous material with a Koji mold and protein hydrolysates produced by these methods were well known in the art at the time of filing the instant application (see EP 0 417 481, EP 0 429 760 and EP 96 201 923.8). The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. The Specification makes clear that certain microorganisms such as koji molds secrete enzymes that act as proteinases and peptidases (see page 1, third and fourth paragraphs), and this protease activity is also well known to include prolidase activity. It is

well known in the art that the function of the areA gene product can be performed by areA homologues or derivatives as set forth in the Specification (see page 3, fifth paragraph; page 6, second paragraph), and in the reference cited therein (Arst et al., Mol. Gen. Genet. 26(1973), 111-141). Therefore, one of skill in the art would recognize what would constitute functional derivatives of an areA gene based on the description in the Specification and what was known in the art (pages 6-8 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. While the method for hydrolyzing protein-containing materials by contacting a proteinaceous material with a Koji mold and protein hydrolysates produced by these methods were well known in the art at the time of filing the instant application, the method for hydrolyzing protein-containing materials by contacting a proteinaceous material with a Koji mold having a modified creA gene is not known at the time of filing the instant application, and the specification does not disclose the use of a Koji mold having a modified creA gene in hydrolyzing a proteinaceous material, nor indicates a protein hydrolysate is produced by the claimed method. Furthermore, while certain microorganisms such as koji molds may secrete enzymes that act as proteinases and peptidases such as prolidase, the specification does not disclose the functional derivatives of areA gene and the use of a functional derivative of areA gene in the claimed method, nor describes the use of creA mutant in combination with an enzyme or microorganism having a prolidase activity in the claimed method. Since the specification has not sufficiently described the claimed methods, the rejection is maintained.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7-8 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 7-8 and 14-17 are indefinite because the claims lack an essential step in the method for hydrolyzing protein-containing materials. The omitted step is the outcome of the process, it is not clear whether the step of providing the Koji mold to the protein-containing materials would hydrolyze the protein-containing materials. Claims 8 and 14-17 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicate claim 7 has been amended to clarify that the method includes the step of providing a Koji mold to protein-containing materials for hydrolyzing the protein-containing materials (pages 8-9 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because the claim does not indicate the outcome of the process, thus it is not clear whether the Koji mold hydrolyzes the protein-containing materials in the claimed method. Therefore, the rejection is maintained.

Conclusion

9. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
November 1, 2006

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/936,367B
Source: IFW16
Date Processed by STIC: 8/30/06

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) **INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,**
2) **TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY**

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO **REDUCE** ERRORED SEQUENCE LISTINGS, **PLEASE** USE THE **CHECKER VERSION 4.4.0 PROGRAM**, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:
http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.
Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.
Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, **EFS Submission User Manual** - ePAVE)
2. **U.S. Postal Service:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. **Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):** U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/10/06

Raw Sequence Listing Error Summary

ERROR DETECTED	SUGGESTED CORRECTION	SERIAL NUMBER: 09/836,367B

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1	Wrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2	Invalid Line Length	The rules require that a line **not exceed 72 characters** in length. This includes white spaces.
3	Misaligned Amino Numbering	The numbering under each 5th amino acid is misaligned. **Do not use tab codes between numbers; use space characters**, instead.
4	Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. **Please ensure your subsequent submission is saved in ASCII text.**
5	Variable Length	Sequence(s)____contain n's or Xaa's representing more than one residue. **Per Sequence Rules, each n or Xaa can only represent a single residue.** Please present the **maximum** number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6	PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. **This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.**
7	Skipped Sequences (OLD RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to **include** the skipped sequences.
8	Skipped Sequences (NEW RULES)	Sequence(s) _____ missing. **If intentional**, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9	Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of **n** or **Xaa**, and which residue n or **Xaa** represents.
10	Invalid <213> Response	Per 1.823 of Sequence Rules, the only **valid** <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is **required** when <213> response is Unknown or is Artificial Sequence. (see item 11 below)
11	Use of <220>	Sequence(s) ___ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section or use "chemically synthesized" as explanation. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32), also Sec. 1.823 of Sequence Rules
12	PatentIn 2.0 "bug"	Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13	Misuse of n/Xaa	"n" can **only** represent a single nucleotide; "Xaa" can **only** represent a single amino acid

IFW16

RAW SEQUENCE LISTING DATE: 08/30/2006
PATENT APPLICATION: US/09/936,367B TIME: 10:18:11

Input Set : N:\RJAVED\09936367.txt
Output Set: N:\CRF4\08302006\I936367B.raw

do not use foreign accent marks. they cannot be processed.

3 <110> APPLICANT: Societe des Produits Nestle
5 <120> TITLE OF INVENTION: creA-gene see below
7 <130> FILE REFERENCE: 80050
C--> 9 <140> CURRENT APPLICATION NUMBER: US/09/936,367B
C--> 10 <141> CURRENT FILING DATE: 2002-01-23
12 <150> PRIOR APPLICATION NUMBER: 99 104 923.0
13 <151> PRIOR FILING DATE: 1999-03-11
E--> 15 <160> NUMBER OF SEQ ID NOS: 2 5 shown (see p. 2)
17 <170> SOFTWARE: PatentIn Ver. 2.1

Does Not Comply
Corrected Diskette Needed

ERRORED SEQUENCES

1) <1107 response differs from CD label. CD label shows "Affolter et al" as applicants

2) <1207 response differs from CD label. CD label shows "Expression of proteolytic enzymes in koji mold in the presence of carbon sources" as the invention title

see pp 2-3, 5

last sequence in submitted file

<210> 5
<211> 6
<212> PRT
<213> consensus of CREA DNA-binding site

invalid response. See item 10 on Error Summary Sheet.

<400> 5
Ser Tyr Gly Arg Gly Gly
1 5

see pp 3, 5 for more errors

RAW SEQUENCE LISTING ERROR SUMMARY DATE: 08/30/2006
PATENT APPLICATION: US/09/936,367B TIME: 10:18:12

Input Set : N:\RJAVED\09936367.txt
Output Set: N:\CRF4\08302006\I936367B.raw

Use of <220> Feature(NEW RULES):
Sequence(s) __are missing the <220> Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial Sequence" or"Unknown". Please explain source of genetic material in <220> to <223> section (See "Federal Register," 6/01/98, Vol. 63, No. 104,pp.29631-32) (Sec.1.823 of new Rules)

Seq#:3,4 (see p. 5 for example)

VERIFICATION SUMMARY DATE: 08/30/2006
PATENT APPLICATION: US/09/936,367B TIME: 10:18:12

Input Set : N:\RJAVED\09936367.txt
Output Set: N:\CRF4\08302006\I936367B.raw

L:9 M:270 C: Current Application Number differs, Replaced Application Number
L:10 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:199 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:3, <213>
ORGANISM:Artificial Sequence
L:199 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:3, <213>
ORGANISM:Artificial Sequence
L:199 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:3,Line#:199
L:211 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:4, <213>
ORGANISM:Artificial Sequence
L:211 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:4, <213>
ORGANISM:Artificial Sequence
L:211 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:4,Line#:211
L:15 M:203 E: No. of Seq. differs, <160> Number Of Sequences:Input (2) Counted (5)

<210> 3

<211> 29

<212> DNA

<213> Artificial Sequence need explanation (see p.3)

<400> 3
cttccccgtc catagtagtg tcccctgtg 29

<210> 4

<211> 29

<212> DNA

<213> Artificial Sequence same error

<400> 4
cacaggggac actactatgg acggggaag 29